IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Norfolk Division

BIONTECH SE, BIONTECH MANUFACTURING GMBH, *and* PFIZER, INC.,

Plaintiffs / Counter Defendants,

v.

CUREVAC SE,

Defendant / Counter Claimant,

and

CUREVAC MANUFACTURING GMBH,

Counter Claimant.

Case No. 2:23-cv-222

MEMORANDUM OPINION & ORDER

This matter is before the Court for claim construction. Having considered the parties' briefs and the exhibits attached thereto, the arguments of counsel at the hearing, and the applicable law, the Court construes the disputed claims as set forth herein.

I. BACKGROUND

This litigation deals with the Comirnaty vaccine, which Plaintiffs BioNTech SE and Pfizer, Inc. (collectively "the plaintiffs") shepherded through development and approval during the height of the COVID-19 pandemic. On August 23, 2021, the

plaintiffs received permission from the United States Food and Drug Administration to begin marketing their vaccine in the United States. ECF No. 1 ¶ 62.

In October of 2021, scientists associated with Defendant CureVac SE ("CureVac"), a German biotechnology company, patented a method for "synthesizing a stabilized mRNA," by increasing the Guanine/Cytosine ("G/C") content of the molecule, ECF No. 226-1 at 31:43–57 (claim 1 in patent 11,135,312 ("the '312 patent")), as well as "a method for treating or preventing infectious disease" by "administering an RNA molecule" with specific characteristics, ECF No. 226-2 at 85:49–63 (claim 1 in patent 11,149,278 ("the '278 patent")).[1] On July 25, 2022, the plaintiffs sued CureVac, seeking a declaratory judgment that they did not infringe the '312 or '278 patents. ECF No. 1 ¶¶ 104–113 (Complaint).[2] CureVac counterclaimed, seeking damages for infringement of those and other related patents. ECF No. 106 ¶¶ 47–239.

The parties presented four terms for construction: "The original coding sequence," "stabilized," and "destabilizing sequence element (DSE)" appear in the '312 patent.[3] "3'-untranslated region (3'-UTR)" appears in the '278, '492, and '920 patents, which are part of a common family.

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[1] This Memorandum Opinion and Order cites to columns and line numbers in the patents where applicable (*e.g.*, "ECF No. 226-2 at 85:49–63") and otherwise to page numbers (*e.g.*, "ECF No. 226-1 at 11"). Page-number citations use the pages assigned by CM/ECF, not the parties' pagination.

[2] The Complaint also included a claim for declaratory judgment of noninfringement of a third patent not before the Court for claim construction. ECF No. 1 ¶¶ 114–118.

II. LEGAL STANDARD

Claim construction is the process of "determining the meaning and scope of the patent claims asserted to be infringed." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). Construing patent claims is a question of law. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 325–26 (2015).

"[T]he claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (quotation marks and citation omitted). Thus, if the parties dispute the scope of the claims, the court must determine their meaning. *See, e.g., Verizon Servs. Corp. v. Vonage Holdings Corp.*, 503 F.3d 1295, 1317 (Fed. Cir. 2007) (Gajarsa, J., concurring in part); *see also Markman*, 517 U.S. at 390. "Claim construction is a matter of [resolving] disputed meanings and technical scope, to clarify and when necessary to explain what the patentee covered by the claims . . . ." *U.S. Surgical Corp. v. Ethicon, Inc.*, 103 F.3d 1554, 1568 (Fed. Cir. 1997).

"There is a heavy presumption that claim terms are to be given their ordinary and customary meaning." *Aventis Pharm. Inc. v. Amino Chems. Ltd.*, 715 F.3d 1363, 1373 (Fed. Cir. 2013) (citing *Phillips*, 415 F.3d at 1312–13 and *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). Courts must therefore "look to the words of the claims themselves . . . to define the scope of the patented

[3] The '278 patent also uses the terms "the original sequence," ECF No. 224-9 at 15:45–58, and "stabilized," *id.* at 36:57, 38:3, 38:13, 46:8. The term is only presented for construction in the '312 patent.

invention." *Id.* (quotation marks and citations omitted). The "ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." *Phillips*, 415 F.3d at 1313; *see Aloc, Inc. v. Int'l Trade Comm'n*, 342 F.3d 1361, 1368 (Fed. Cir. 2003). The "person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." *Phillips*, 415 F.3d at 1313.

Intrinsic evidence is the primary resource for claim construction. *See Power-One, Inc. v. Artesyn Techs., Inc.*, 599 F.3d 1343, 1348 (Fed. Cir. 2010) (citing *Phillips*, 415 F.3d at 1312); *Bell Atl. Network Servs., Inc. v. Covad Commc'ns Group, Inc.*, 262 F.3d 1258, 1267 (Fed. Cir. 2001). Intrinsic evidence includes the claims, the rest of the specification, and the prosecution history. *Phillips*, 415 F.3d at 1312–13; *Bell Atl. Network Servs.*, 262 F.3d at 1267.

For certain claim terms, "the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges." *Phillips*, 415 F.3d at 1314. In those circumstances, "claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words." *Id.* But for claim terms whose meanings are less obvious, courts consider "those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean . . . [including] the words of the claims themselves, the remainder of the specification, the prosecution history, *and* extrinsic evidence concerning relevant scientific principles, the meaning of

technical terms, and the state of the art." *Phillips*, 415 F.3d at 1314; *see Medrad, Inc. v. MRI Devices Corp.*, 401 F.3d 1313, 1319 (Fed. Cir. 2005) ("We cannot look at the ordinary meaning of the term . . . in a vacuum. Rather, we must look at the ordinary meaning in the context of the written description and the prosecution history.")

III. CLAIM CONSTRUCTION

Prior to submitting their opening claim construction briefs, the parties exchanged summaries of their proposed constructions of the disputed terms. The plaintiffs disclosed their proposed constructions, but at this stage, CureVac did not. CureVac asserted that each term should be given its plain and ordinary meaning to a person of ordinary skill in the art, but it did not define what qualifications the ordinarily skilled artisan would have, nor did it spell out what it believed the plain and ordinary meanings of the disputed terms to be. The parties then submitted their opening briefs simultaneously. ECF Nos. 224 (CureVac), 225 (plaintiffs). Thus, the plaintiffs were forced to advance their own proposed constructions without responding to the substance of CureVac's proposals.

In its own opening brief, CureVac disclosed what it believes constitutes a person of ordinary skill in the art: "someone with a Ph.D. or equivalent degree and several years of research experience in the relevant field." ECF No. 224 at 9 n.2; *see id.* at 15 (argument). In their reply brief, the plaintiffs do not dispute CureVac's framing of a person of ordinary skill in the art. *See generally* ECF No. 295. Thus, the Court finds that, in the context of the patents in suit, a person of ordinary skill in the art at the time of the claimed invention was someone with a Ph.D. or equivalent

degree and several years of research experience in the field of nucleic acid research and development.

CureVac also presented definitions it asserts capture the plain and ordinary meanings of each of the disputed terms. ECF No. 224 at 17, 23, 25, 31. Again, in their reply brief, the plaintiffs do not dispute that CureVac's proposed definitions are in fact the meanings a person of ordinary skill in the art would attribute to the disputed terms in the context of the patents. Rather, the plaintiffs argue that for each term, the patentees provided a lexicographic definition that should control the Court's construction. *See generally* ECF No. 295. Based on (1) its review of extrinsic evidence as a general primer on the science, (2) the technical background provided by both parties, and (3) the fact that CureVac's framings are not contested, the Court finds that the plain and ordinary meanings of the disputed terms are as CureVac claims they are.

CureVac asserts that because the terms should be given their plain and ordinary meanings to a person of ordinary skill in the art, the terms do not require construction. ECF No. 224 at 9 ("The Court should . . . hold as a matter of law that each term should be given its plain and ordinary meaning, which is apparent from the terms themselves, without any further explanation of their meaning."). Because the parties dispute the meanings of the four terms presented for construction, the Court finds it prudent to construe all four terms, even if that construction ultimately results in giving each term its plain and ordinary meaning.

A. "the original coding sequence"

The plaintiffs assert that "the original coding sequence" means "the wild type coding sequence," which in turn refers to "the naturally occurring mRNA sequence that originally existed in nature with the 'A' and 'U' bases before the introduction of the claimed 'G' and 'C' modifications." ECF No. 225 at 16–17. CureVac argues that the term does not require construction, because a person of ordinary skill in the art would understand that it refers to "the coding sequence of the mRNA before it is modified by increasing its G/C content, according to the claimed method." ECF No. 224 at 23. Specifically, CureVac contends that the plaintiffs' proposed construction cannot be right, because "the '312 patent describes using the claimed invention to modify 'original sequences' that are ***not*** naturally[]occurring sequences found in nature." ECF No. 290 at 11.[4] The crux of the dispute is whether "original coding sequence" refers only to sequences that occur in nature or whether an artificial coding sequence can also be the "original."

The Court first looks to whether the claim language allows for the possibility that modifications to increase an mRNA molecule's G/C content can be applied to coding sequences that do not occur in nature. Claim 1, which is representative, describes "[a] method for producing a stabilized mRNA molecule . . . wherein the

[4] CureVac also asserts that substituting "the easily[]understood claim term 'original' with the more[]complicated phrase 'wild type' . . . . [would] likely result in unnecessary jury confusion." ECF No. 290 at 16. Because the Court does not adopt the plaintiffs' proposed construction, it need not address this aspect of CureVac's argument.

stabilized mRNA molecule . . . *comprises* a coding sequence that has an increased Guanine/Cytosine (G/C) content relative to the original coding sequence . . . .” ECF No. 226-1 at 31:43–48 (emphasis added). “‘[C]omprising’ in a method claim indicates that the claim is open-ended and allows for additional steps.” *Solvay S.A. v. Honeywell Int’l Inc.*, 742 F.3d 998, 1005 (Fed. Cir. 2014); *Invitrogen Corp. v. Biocrest Mfg., L.P.*, 327 F.3d 1364, 1368 (Fed. Cir. 2003). Thus, the method claimed in the ’312 patent is not limited to producing an mRNA molecule with “increased Guanine/Cytosine (G/C) content” in the original coding sequence. Other modifications can be made without taking the final product outside the scope of the patent. ECF No. 226-1 at 31:47.

However, this would be true whether “original” meant “wild type” or not. In the context of the claims, “the original coding sequence” is simply the thing to which the “stabilized mRNA” is compared. *See* ECF No. 226-1 at 31:47–48 (“increased Guanine/Cytosine (G/C) content relative to the original coding sequence encoding the polypeptide”), 54–57 (“enhanced expression of the polypeptide compared to mRNA having the original coding sequence encoding the polypeptide”). Nothing in the claim language limits the source of “the original coding sequence” to naturally occurring molecules. Therefore, a person of ordinary skill in the art, reading the claims alone, would understand the term to have its plain an ordinary meaning: “the coding sequence before it is modified using the claimed method.” ECF No. 224 at 17.

The specification supports this construction. “[S]pecification explanations may lead one of ordinary skill to interpret a claim term more narrowly than its plain

meaning suggests." *Computer Docking Station Corp. v. Dell, Inc.*, 519 F.3d 1366, 1374 (Fed. Cir. 2008). But for a specification to suggest such a narrowing of the claim language, it must include "expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope" suggested by the plain and ordinary meaning. *Thorner v. Sony Computer Ent. Am. LLC*, 669 F.3d 1362, 1366 (Fed. Cir. 2012); *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1325 (Fed. Cir. 2002); *see Home Diagnostics, Inc. v. LifeScan, Inc.*, 381 F.3d 1352, 1358 (Fed. Cir. 2004) ("Absent a clear disavowal or contrary definition in the specification or the prosecution history, the patentee is entitled to the full scope of its claim language."); *see also Computer Docking Station Corp.*, 519 F.3d at 1374 ("For example, repeated and definitive remarks in the written description could restrict a claim limitation to a particular structure."). For the reasons explained below, no clear narrowing exists in the '312 specification with respect to "the original coding sequence."

It is true that "original" and "wild type" are sometimes "used to refer to the same mRNA sequence." ECF No. 225 at 17 (quoting ECF No. 226-1 at 4:31–32 and 5:7–9).[5] But that does not necessarily mean that the two terms have the same

[5] To demonstrate this, the plaintiffs splice together two phrases separated by more than 35 lines of text:

> [V]arious possibilities for modifying the mRNA sequence compared to the wild type sequence are feasible . . . to increase the G/C content of a modified mRNA compared to the original sequence.

ECF No. 226-1 at 4:31–32 and 5:7–9. This is perhaps a red flag that the plaintiffs' proposed interpretation is a stretch.

meaning. Specifically, it does not rule out the possibility that "original" is to rectangle as "wild type" is to square—that is, the possibility that some but not all sequences to which the claimed process can be applied occur in nature. The plaintiffs point to a phrase "the original (wild type) sequence," which appears twice in the specification. ECF No. 225 at 17–18 (quoting ECF No. 226-1 at 5:10, 16:67). But again, this formulation is ambiguous: The parenthetical could define the preceding word[6] or offer explanatory information about a particular original sequence, precisely because not all original sequences are wild-type sequences.[7] Thus, it does not answer the question presented here.

To decide whether the specification treats "original" and "wild type" interchangeably, the Court must determine whether the patent contemplates applying the claimed process to artificial nucleic acid sequences. There are at least two instances where the '312 patent describes applying the claimed process to a sequence that undergoes more than one modification. First, the specification makes clear that the claimed process can be applied to multiple codons in the same molecule, to achieve greater stability. *See* ECF No. 226-1 at 5:6–8 ("The substitutions listed above may be used individual hand [sic: individually and] in all possible combinations in order to increase the G/C content of a modified mRNA compared to the original sequence."). Second, Figure 1D illustrates how the claimed process can be applied to

[6] This phrasing is commonly used to provide translations. (*E.g.*, "Joe Torre was the manager (head coach) of the Yankees.")

[7] This phrasing is commonly used to specify an intended meaning when multiple meanings are possible. (*E.g.*, "We watched *Star Wars* (the original).")

a nucleic acid molecule to which another modification is also made. *See id.* at 11 (showing increased G/C content in an influenza molecule that is also modified by inserting a portion of human sequence).

In order for these passages to support a construction that equates "original" with "wild type," they would have to require the claimed process to be applied before any other modification is made. However, "unless the steps of a method claim actually recite an order, the steps are not ordinarily construed to require one." *Mformation Techs., Inc. v. Rsch. in Motion Ltd.*, 764 F.3d 1392, 1398–99 (Fed. Cir. 2014) (quoting *Interactive Gift Express, Inc. v. Compuserve Inc.*, 256 F.3d 1323, 1342 (Fed. Cir. 2001)) (cleaned up). Instead, a claim "requires an ordering of steps" when either (1) "the claim language, as a matter of logic or grammar, requires that the steps be performed in the order written," or (2) "the specification directly or implicitly requires an order of steps." *Mformation Techs.*, 764 F.3d at 1398 (quotation marks and citations omitted); *see, e.g.*, *Function Media, LLC v. Google, Inc.*, 708 F.3d 1310, 1320 (Fed. Cir. 2013) (a claim that covers a method for "processing" an "electronic advertisement" required "the creation of the ad" to "happen before the processing begins"). Neither circumstance arises here.

The specification does not explicitly dictate an order of operations in either of the passages that contemplate multiple modifications. It is possible to read the passage about "all possible combinations" of substitutions such that all C/G substitutions happen at the same time, so that the claimed process is never applied to an artificial molecule. But it is equally possible that the substitutions could occur

serially, such that the second change or round of changes is applied to a molecule that did not exist in nature. *See* ECF No. 226-1 at 5:6–35.

Similarly, the annotations to Figure 1D do not state whether the diagrammed molecule's G/C content was increased before or after the human sequence was inserted into the influenza virus—*i.e.*, whether the claimed process was applied to a wild-type or artificial sequence. ECF No. 226-1 at 11. The context of Figure 1D softly implies that the claimed process was applied to a naturally occurring molecule: The illustration immediately prior shows the same influenza gene with increased G/C content but without the human sequence, which suggests that the figures might be presented in sequence, so that the modification shown in Figure 1C would be applied to the wild-type influenza molecule, and the human sequence would be inserted after the claimed process was complete. *See id.* at 11. But this is far from an explicit disavowal, so it is not enough to limit the scope of the claims. *See Thorner*, 669 F.3d at 1366 ("The standard for disavowal of claim scope is [] exacting."). Thus, the specification supports the conclusion that the meaning of "the original coding sequence" is not limited to sequences occurring in nature.

The '312 patent's prosecution history does not disrupt this conclusion. In response to a proposed amendment that ultimately replaced "native" with "original" in two claims, the examiner said that "[t]he specification uses the terms 'original' and 'wild type' interchangeably." ECF No. 226-13 at 2. But the *examiner's* statement is insufficient to limit the claim. *See Ancora Techs., Inc. v. Apple, Inc.*, 744 F.3d 732, 737 (Fed. Cir. 2014) (acknowledging that a patent examiner's statement can be incorrect

and holding that such a statement does not govern construction where the "applicants were clear.") All the *patentees* said about the change was that it was meant "to clarify the language of the claim." ECF No. 226-10 at 6. The Court cannot say that the amendment rendered the meaning of "original" clear. However, the fact the patentees thought "original" captured their intent better than "native"—a word which more closely aligns with the meaning of "wild type," in that it connotes something natural—cuts against the conclusion that CureVac used "original" and "wild type" interchangeably.

The prosecution history of another patent in the same family sheds further light on the patentees' intent, suggesting that the patentees sought to *avoid* defining the coding sequence that exists before the claimed process is applied as a "wild type" sequence. While the PTO was examining the '312 patent application, the examiner on the '691 patent (which shares the same specification as the '312 patent) "proposed amending [three claims] to replace the word 'reference' with the word 'wild type.'" ECF No. 226-13 at 2. The examiner explained that "'reference' is reasonably interpreted as any original/wild type sequence *or any other synthetically generated or mutant sequence*"—in other words, the term "reference" did not limit the claims to sequences occurring in nature. *Id.* (emphasis added). The patentees "requested the replacement of 'a reference' with 'an original'" instead. *Id*. Though the examiner accepted that alternative because *they* believed "[t]he specification uses the terms 'original' and 'wild type' interchangeably," *id.*, there is no indication that the *patentees* shared that view. If they had, one would imagine they would have agreed to the

examiner's suggestion rather than requesting a substitution that preserved a broader definition of the sequence that exists before the claimed process is applied. While the patentees' subjective intent has no effect in the abstract, when such intent is expressed in the text of the patent, it can provide insight into how a person of ordinary skill in the art would read the claims. *See Vitrionics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1584 (Fed. Cir. 1996) ("Nor may the inventor's subjective intent as to claim scope, *when unexpressed in the patent documents*, have any effect.") (emphasis added). Accordingly, the negotiation that led to a *rejection* of "wild type" in favor of "original" in the final text of the specification indicates that a person of reasonable skill in the art would not equate the two terms; they would give "original" its plain and ordinary meaning.

Finally, the language of the '278 specification provides context that confirms that the patents in the family contemplate a difference between "original" and "wild type" coding sequences. The '278 patent claims "a method for treating or preventing an infectious disease" with an mRNA therapeutic that comprises "at least one open reading frame . . . encoding an antigen from a pathogen associated with the infectious disease." ECF No. 226-2 at 85:50–55. In other words, this patent deals with a method that employs a coding sequence from an "infectious disease," which inherently occurs in nature. The '278 specification contains a passage that is identical to the "all possible combinations" passage discussed above (ECF No. 226-1 at 5:6–35) except that '278 says "wild type" instead of "original":

> The substitutions listed above can be used either individually or in all possible combinations to increase the

> G/C content of the open reading frame of the inventive artificial nucleic acid molecule as defined herein, compared to its particular wild type open reading frame (*i.e.*, the original sequence). Thus, for example, all codons coding for Thr occurring in the wild type sequence can be modified to ACC (or AGG).

ECF No. 226-2 at 47:23–29. While the plaintiffs (and perhaps the examiner) might view this as evidence that all the patents in this family use "original" and "wild type" interchangeably, the Court cannot agree. It is no accident that "wild type" appears in the specification for a method that uses "an antigen from a pathogen associated with [a naturally occurring] infectious disease," *id.* at 85:53–55, whereas "original" appears in an otherwise identical passage in the specification for a method that does not require a building-block from a real-life pathogen, *see* ECF No. 226-1 at 31:43–56. Thus, in the context of the broader patent family, it is evident that not all "original" nucleic acid sequences are "wild type" sequences.[8]

[8] Claim construction is "a contextual interpretation of language" and "not a policy-driven inquiry." *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1339 (Fed. Cir. 2005). Thus, "the scope of patent claims can neither be broadened nor narrowed based on abstract policy considerations regarding the effect of a particular claim meaning." *Id.* Rather, courts "must construe claims without considering the implications of covering a particular product or process." *Id.* at 1340. However, when adopting the plain and ordinary meaning of a term incidentally avoids an absurd result, that is noteworthy, because it confirms the conclusion that a person of reasonable skill in the art would understand the term to have its plain and ordinary meaning in the context of the patent. Here, construing "the original coding sequence" as "the wild type sequence" would mean there could be no infringement as long as *any* modification was made to the wild-type coding sequence before the claimed process was applied. This would create a simple roadmap for would-be infringers. The plain and ordinary meaning of the term avoids that absurd outcome.

Taking all the intrinsic evidence together, the Court concludes that a person of ordinary skill in the art would understand "the original coding sequence" in the '312 patent to have its plain and ordinary meaning: the coding sequence before it is modified using the claimed method.

B. "stabilized"

The plaintiffs argue that "stabilized" should be construed to mean "to maintain at a given or unfluctuating level or quality." ECF No. 225 at 21. CureVac asserts that the claim does not require construction, because a person of ordinary skill in the art would understand that "a 'stabilized' mRNA molecule is one that is more stable than an mRNA molecule with an unmodified 'original coding sequence' . . . ." ECF No. 224 at 17.

The claims describe "[a] method for producing a stabilized mRNA." ECF No. 226-1 at 31:44. A person of ordinary skill in the art would understand that "stabilized" means more stable, as opposed to fixed or unfluctuating, because the claims deal with an inherently unstable molecule. *See* ECF No. 556-1 at 2:47–48 (describing "the natural decomposition of mRNA in the cytoplasm of cells").

This interpretation is consistent with the specification, which makes clear that RNA's rapid rate of breakdown in the body is the central problem the claimed process aims to solve. *See* ECF No. 226-1 at 2:26–27 ("RNA is degrading rapidly in vivo"). Thus, such a person would understand that a "stabilized" mRNA molecule is one that degrades more slowly than its unmodified counterpart. *See id.* at 2:37–41 ("Since RNA is normally found one [sic] very unstable in solution, up to now RNA could not

be used or used only very inefficiently as a therapeutic . . . ."), 3:1–3 ("Certain measures have been proposed in the prior art to improve the stability of RNA and thereby enable its use as a therapeutic agent or RNA vaccine.").

The plaintiffs contend that the patentees provided a lexicographic definition of "stabilized," in order to overcome the PTO's rejection on the grounds that the term was vague, and they are therefore bound to that definition even though it varies from the plain and ordinary meaning. ECF No. 225 at 21–23; *See Phillips*, 415 F.3d at 1316 (When "the specification [reveals] a special definition given to a claim term . . . that differs from the meaning it would otherwise possess," that definition controls.) *Braintree Lab'ys, Inc. v. Novel Lab'ys, Inc.*, 749 F.3d 1349, 1356 (Fed. Cir. 2014) (a "patentee's lexicography must govern the claim construction analysis"); *Honeywell Inc. v. Victor Co. of Japan*, 298 F.3d 1317, 1323–24 (Fed. Cir. 2002) (recognizing that "a definition offered during prosecution [that] is made in response to a rejection" can "limit[] the scope of the claim, preventing the patentee from later recapturing what was previously surrendered").

But a patent applicant's argument about the meaning of a term, in response to a rejection, does not necessarily amount to lexicography. "To act as its own lexicographer, a patentee must clearly set forth a definition of the disputed claim term *other than its plain and ordinary meaning* and must clearly express an intent to *redefine* the term." *Kyocera Senco Indus. Tools Inc. v. Int'l Trade Comm'n*, 22 F.4th 1369, 1378 (Fed. Cir. 2022) (emphasis added, quotation marks and citation omitted). Moreover, "a definition offered during prosecution [that] is made in response to a

rejection[]" only "limits the scope of the claim" when it "is entered in conjunction with a narrowing amendment." *Honeywell*, 298 F.3d at 1323–24.

Here, the patentees' brief before the PTO did quote the definition the plaintiffs point to, but they offered the definition to provide an "example" of the meaning a person of ordinary skill in the art would give the term—not to "redefine the term." ECF No. 226-7 at 4; *Kyocera Senco*, 22 F.4th at 1378; *see also* ECF No. 226-7 at 5 (discussing the millions of Google results for the term "stabilized mRNA" and noting that "[w]hile all of these hits might not provide the same exact definition, it is without question that this term is well[]known in the field[] and therefore would be presumed to have a general art-accepted definition"). Thus, the patentees did not enter a narrowing amendment, and no definition of "stabilized" appears in the patent. *See Honeywell*, 298 F.3d at 1323–24. In short, the prosecution history demonstrates that the patentees did not provide a lexicographic definition of "stabilized"; they merely argued the term's plain and ordinary meaning.

Finding that the patentees did not provide a lexicographic definition of "stabilized," the Court will give the term its plain and ordinary meaning to a person of ordinary skill in the art: A "stabilized" mRNA molecule is one that is more stable than an mRNA molecule with an unmodified original coding sequence.

C. "destabilizing sequence element (DSE)"

The plaintiffs aver that "destabilizing sequence element" should be construed to mean an "mRNA sequence to which signal proteins can bind and thereby regulate the enzymatic degradation of the mRNA in vivo." ECF No. 225 at 24. CureVac argues

a person of ordinary skill in the art would understand the term to mean "an element of the sequence that . . . makes the mRNA less stable" or "a sequence which, when eliminated from the mRNA by the claimed method, results in an mRNA that is more stable." ECF No. 224 at 26. Thus, the central dispute is whether the binding of signal proteins defines elements of an mRNA molecule as DSEs.

The claims describe a process for stabilizing an mRNA molecule by increasing the G/C content, where "said increase in relative G/C content results in the elimination of at least one destabilizing sequence element (DSE) . . . ." ECF No. 226-1 at 31:52–54. The claim language does not prescribe any identifying features or functions of a DSE beyond its nominal "destabilizing" nature. Thus, it is apparent from the claim language that a DSE is simply an element of the mRNA sequence that makes the molecule less stable (or whose removal makes the molecule more stable).

The specification bolsters that reading, by explaining that DSEs can "be mutated or changed to generate a modified mRNA having improved properties." ECF No. 226-1 at 6:53–56. The specification also states: "Sequences of eukaryotic mRNAs frequently include destabilizing sequence elements (DSE) to which signal proteins can bind and thereby regulate the enzymatic degradation of the mRNA in vivo." *Id.* at 6:43–46. The plaintiffs contend that this sentence amounts to a lexicographic definition of DSE. The Court disagrees for several reasons.

First, this passage is devoid of the type of language that patents typically use to introduce definitions. *Compare* ECF No. 226-1 at 6:43–46 *with Kyocera Senco*, 22 F.4th at 1378 (recognizing a definition introduced by "referred to herein") (alteration

accepted and citation omitted) *and Abbott Labs v. Andrx Pharms., Inc.*, 473 F.3d 1196, 1210 (2007) (same, where definitions were introduced with "as used herein, means") (quotation marks omitted). Second, the patent uses such definitional language elsewhere, but never with reference to DSEs. *See, e.g.,* ECF No. 226-1 at 14:19–25 ("As used herein, the term 'genetic construct' refers to . . . ."), 14:26 ("As used herein, the term 'expressible form' refers to . . . ."), 14:30–31 ("As used herein, the term 'genetic vaccine' refers to . . . ."). Third, the sentence lacks a comma where one would be required to render the "signal proteins" phrase definitional.[9] ECF No. 226-1 at 6:43–46.

Finally, a definition of DSE that required binding with signal proteins would be inconsistent with other portions of the specification. The specification describes "DSEs located anywhere in an mRNA, including the coding region and in the non-translated regions (3' and/or 5' UTR)." ECF No. 226-1 at 6:53–55; *see also id.* at 6:57–59 ("Such destabilizing sequences are for example AU-rich sequences ("AURES") that occur in 3'-UTR regions of a number of unstable mRNAs . . . ."). Because signal proteins only bind to sequences in coding regions—not to those in untranslated

[9] "[T]o which signal proteins can bind and thereby regulate the enzymatic degradation of the mRNA in vivo" is a relative clause. ECF No. 226-1 at 6:43–46. Without a comma after "(DSE)" (*i.e.*, "destabilizing sequence elements (DSE) to which signal proteins can bind . . ."), the clause is restrictive—meaning it tells the reader which type of DSE the sentence is talking about. *Id.* at 6:43–44. (*E.g.*, I have two sisters. This is my sister Jane.) If a comma were added after "(DSE)," the clause would be nonrestrictive (*i.e.*, "destabilizing sequence elements (DSE), to which signal proteins can bind . . .")—meaning, in this context, that it would define the preceding term. *Id.* (*E.g.*, My other sister, Jill, lives in California.").

regions—a construction that requires signal-protein binding would be inconsistent with the language of the specification.

Having considered all the intrinsic evidence, the Court will construe "destabilizing sequence element (DSE)" to have its plain and ordinary meaning to a person of ordinary skill in the art: an element of an mRNA sequence that makes the mRNA less stable and which, when eliminated using the claimed method, results in an mRNA that is more stable.

D. "3'-untranslated region (3'-UTR)"

The '278, '492, and '920 patents (collectively "the poly(A) patents") deal with a method for inserting an artificial sequence of non-adenine nucleotides into the poly(A) sequence at the 3' end of an mRNA molecule, which causes the mRNA to produce more protein. *See, e.g.*, ECF No. 224-10 at 85:61–87:9 (claim 1 of the '492 patent). All the claims in the poly(A) patents require:

> a heterologous 3'-untranslated region (3'-UTR) comprising at least a first and a second poly(A) sequence, wherein
>
> (i) the first poly(A) sequence comprises at least [X] adenine nucleotides; and
>
> (ii) (ii) the second poly(A) sequence comprises at least [Y] adenine nucleotides,
>
> wherein the first and the second poly(A) sequences are separated by a nucleic acid sequence comprising [Z] nucleotides and having no more than 2 consecutive adenine nucleotides.

Id. at 86:61–87:4.[10]

[10] Claim 1 in the '492 patent is quoted here and used throughout this section as representative of the claims in all the poly(A) patents. X and Y represent whole

The plaintiffs ask the Court to construe "3'-untranslated region" to mean "the sequence of mature mRNA which is located between the stop codon of the protein coding region, preferably immediately 3' to the stop codon of the protein coding region, and the poly(A) sequence of the mRNA and which is not translated to any protein." ECF No. 225 at 26. CureVac argues that a person of ordinary skill in the art would understand the term to have its plain and ordinary meaning in the context of the patents: "the region at the 3'[]end of the mRNA that does not get translated." ECF No. 224 at 31. The central dispute is whether "3'-UTR" excludes the poly(A) sequence at the 3' terminus of an mRNA—*i.e.*, the region known as the "poly(A) tail."

The language applicable to every claim in the poly(A) patents dictates that, whatever a 3'-UTR is in the context of the poly(A) patents, it must be capable of "comprising at least a first and a second poly(A) sequence." ECF No. 224-10 at 86:61–62. The plaintiffs' proposed construction, which references a singular poly(A) sequence (*i.e.*, "*the* poly(A) sequence of the mRNA") cannot be squared with this language. Moreover, at least one dependent claim calls for "one of the poly(A) sequences" in the 3'-UTR to be "located at the 3' terminus of the RNA molecule." ECF No. 224-9 at 86:56–58 ('278 patent, claim 5). Thus, the claims require a construction of "3'-UTR" that allows for inclusion of the poly(A) tail. *See Capital Mach. Co., Inc. v. Miller Veneers, Inc.*, 524 Fed. App'x. 644, 647 (Fed. Cir. 2013) (unpublished) ("When

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numbers and Z represents a whole number or a range of whole numbers. Not every claim is ordered identically, but all contain the same basic requirements for the 3'-UTR.

construing claim in patents that derive from the same parent application and share common terms, [courts] must interpret the claims consistently across all asserted patents.") (quoting *NTP, Inc. v. Research in Motion, Ltd.*, 418 F.3d 1282, 1293 (Fed. Cir. 2005), *abrogated on other grounds by Zoltek Corp. v. United States*, 672 F.3d 1309, 1313 (Fed. Cir. 2012) (en banc) (quotation marks omitted). Accordingly, a person of ordinary skill in the art reading the claims would understand "3'-UTR" to refer to the region at the 3' end of the mRNA that does not get translated—including the poly(A) tail.

This reading is consistent with the specification, where the patent lays out in detail the range of possible meanings for the term. In a section devoted to "definitions [that] may be read on each and every embodiment of the invention," ECF No. 224-10 at 6:65–7:1, the specification explains that 3'-UTR has a "[g]eneral[]" meaning and a "[t]ypical" meaning. *Id.* at 16:53–60. "Generally, the term '3'-UTR' refers to a part of the artificial nucleic acid molecule, which is located 3' (*i.e.* "downstream") of an open reading frame and which is not translated into protein." *Id.* at 16:53–56. The construction suggested by the claim language, as described above, fits this definition. "Typically, a 3'-UTR is the part of an mRNA, which is located between the protein coding region . . . and the poly(A) sequence of the mRNA." *Id.* at 16:56–57. This definition conflicts with the claim language, because it excludes the poly(A) tail. Thus, it is best understood as an acknowledgement of the plain and ordinary meaning of "3'-UTR," which differs slightly from the meaning in the context of the patent.

The specification goes on to outline features that "may comprise" the 3'-UTR "in the context of the invention." ECF No. 224-10 at 16:60–17:2. These features do not define the 3'-UTR in the context of the patent, but they do reinforce the conclusion that "3'-UTR" in the context of the patent necessarily differs from a naturally occurring 3'-UTR, because the claims deal with artificial nucleic acid sequences. *See, e.g.*, *id.* at 16:60–64 (features of the 3'-UTR in the context of the claims "may comprise . . . sequence elements derived from . . . several (unrelated) naturally occurring genes"). Thus, the "may comprise" passage confirms that the broader, "general[]" definition of "3'-UTR," rather than its "typical" definition, applies in the context of the patent. *Id.* at 16:53–60. This passage concludes by stating: "A 3'-UTR of the mRNA is not translated into an amino acid sequence." *Id.* at 17:1–2. This sentence reaffirms the conclusion that the only definitional features of "3'-UTR" in the context of the patent are that it is "located 3' (*i.e.* "downstream") of an open reading frame and [] is not translated into protein." *Id.* at 16:53–56.[11]

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[11] The specification next outlines how "[t]he 3'-UTR sequence is generally encoded" and "transcribed . . . during the gene expression process." ECF No. 224-10 at 17:2–4. From this section, the plaintiffs extract the following sentence, which they argue provides the appropriate construction of "3'-UTR":

> In the context of the present invention, a 3'-UTR corresponds to the sequence of a mature mRNA which is located between the the [sic] stop codon of the protein coding region, preferably immediately 3' to the stop codon of the protein coding region, and the poly(A) sequence of the mRNA.

Id. at 17:12–17. Contrary to the plaintiffs' assertion, this is not a definition of "3'-UTR." "Corresponds to" does not mean "is defined as." In fact, the very next sentence defines "corresponds to":

The plaintiffs point the Court to a molecular biology textbook and to prior-art publications by the inventors of the poly(A) patents that illustrate that "3'-UTR" is more commonly understood to terminate before the poly(A) tail begins. ECF No. 225; *see* ECF No. 226-18 at 32 (textbook chapter defining "3'-UTR" as "the region of RNA that extends from the stop codon that terminates protein synthesis to the start of the poly[(A)] tail"); ECF No. 226-19 at 8 (article co-authored by patent inventor, stating that "translational efficacy of NRA-encoded antigens was optimized by modifications of the length and structure of the poly(A) fail as well as the 3'[-]untranslated region [] between opening reading frame [] and poly(A) tail"); ECF No. 226-20 at 4 (article co-authored by two inventors, including the phrase "the 3'-untranslated region that resides between [the open reading frame] and the poly[(A)] tail"). These sources provide guidance as to what a "3'-UTR" is in the abstract, but they do not inform the Court's construction of the term in the context of the claims. *See Genuine Enabling Tech. LLC v. Nintendo Co.*, 29 F.4th 1365, 1373 (Fed. Cir. 2022) ("Extrinsic evidence is to be used for the court's understanding of the patent, not for the purpose of varying or contradicting the terms of the claims.") (quoting *Markman*, 52 F.3d at 981) (alteration rejected and quotation marks omitted). The Court is only permitted to rely on extrinsic evidence where "a disputed claim term remains ambiguous after analysis

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> "The term 'corresponds to' means that the 3'-UTR sequence may be an RNA sequence, such as in the mRNA sequence used for defining the 3'-UTR sequence, or a DNA sequence, which corresponds to such RNA sequence."

ECF No. 224-10 at 17:18–22.

of the intrinsic evidence." *Actelion Pharms. LTD v. Mylan Pharms, Inc.*, 85 F.4th 1167, 1174 (Fed. Cir. 2023) (quotation marks and citation omitted). For the reasons explained above, that is not the case here.

Based on the claim language and the specification,[12] the Court construes "3'-untranslated region (3'-UTR)" as: a part of the artificial nucleic acid molecule, which is located 3' (*i.e.* "downstream") of an open reading frame and which is not translated into protein.

IV. CONCLUSION

For the reasons discussed, the Court adopts the constructions set forth above as to the four disputed claim terms in the asserted patents.

The Clerk is **DIRECTED** to send a copy of this Memorandum Opinion and Order to all counsel of record.

IT IS SO ORDERED.

/s/
Jamar K. Walker
United States District Judge

Norfolk, Virginia
July 30, 2024

[12] The plaintiffs also point to a portion of the prosecution history in which the examiner discussed a prior-art statement that created a distinction between the 3'-UTR and the poly(A) tail. ECF No. 225 at 28 (citing ECF No. 226-17 at 7). Because there is no indication that this prior-art statement was adopted as a definition in the patent, it is best understood as extrinsic evidence dressed up as prosecution history. Therefore, it does not contravene the Court's construction, which is based on the intrinsic record.